UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY CASES LITIGATION	)	MDL NO. 13-02419-RWZ

BEFORE: THE HONORABLE JENNIFER C. BOAL

MOTION HEARING
AND
STATUS CONFERENCE

John Joseph Moakley United States Courthouse
Courtroom No. 12
One Courthouse Way
Boston, MA 02210

December 17, 2015
11:30 a.m.

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(Appearances continued on the next page.)

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APPEARING TELEPHONICALLY:

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ALSO PRESENT:

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P R O C E E D I N G S

(The following proceedings were held in open court before the Honorable Jennifer C. Boal, Magistrate Judge, United States District Court, District of Massachusetts, at the John J. Moakley United States Courthouse, One Courthouse Way, Boston, Massachusetts, on December 17, 2015.)

COURTROOM DEPUTY CLERK YORK: The Honorable Jennifer C. Boal presiding. You may be seated.

Today is December 17th, 2015. We're on the record in the matter of NECC. Would counsel please state your names for the record.

MS. JOHNSON: Good morning, your Honor. Kirsten Johnson for the plaintiffs.

MR. STRANCH: Good morning, your Honor. Gerard Stranch on behalf of the Plaintiffs' Steering Committee.

MS. MEEDER: Good morning, your Honor. Jessica Meeder on behalf of the plaintiffs.

MR. ELLIS: Good morning, your Honor. Rick Ellis for plaintiffs.

MR. TARDIO: Good morning, your Honor. Chris Tardio and C.J. Gideon.

MR. WOLK: Good morning, your Honor. Christopher Wolk on behalf of the Premier defendants.

MR. KIRBY: Good morning, your Honor. Gregory Kirby on behalf of the Box Hill defendants.

THE COURT: Anyone else?

(No response.)

THE COURT: All right. Good morning, everyone.

We do have some folks on the phone. So, I would ask, in accordance with our usual custom, if you could stay seated and pull the microphone towards you if you are, in fact, speaking.

So, Ms. Johnson, if you would like to take us through the schedule.

MS. JOHNSON: Thank you, your Honor.

There are four motions that the Court had either set for argument today or for which plaintiffs are requesting argument. We've put them in no particular order, but the first one on the agenda -- well, the first number one on the agenda -- we have two -- is the Tennessee Clinic Defendants' motion for protective order relating to the depositions of the six Howell Allen treating physicians.

THE COURT: All right. So, I'll hear from -- is it you, Mr. Tardio?

MR. TARDIO: Yes, ma'am. Thank you, your Honor.

This is our motion for protective order. I know that the Court -- the Court heard the refrain from Ameridose many times in these cases that we didn't compound the medication. We didn't sell the medication. We didn't distribute the medication. And the same principle applies here.

THE COURT: Ameridose is in a completely different position than a treating physician.

MR. TARDIO: But they still hold relevant information. They still hold relevant information. I'm not arguing that these physicians don't hold relevant information. Our position is that the Court must make a case-by-case or issue-by-issue analysis and determine whether the information they hold to be elicited in depositions is valuable enough to justify the burden and expense of six depositions, dozens of hours.

THE COURT: Just so I can understand, what is your client's standing to bring this motion?

MR. TARDIO: Well, I think that any party can bring a motion for protective order.

THE COURT: Usually there has to be -- if it's not the individual itself, usually there has to be some particularized reason, like it's going to waive your privilege, perhaps.

MR. TARDIO: Well, we represent Howell Allen and these are members of Howell Allen and I think that gives us standing --

THE COURT: Is Howell Allen a part of the other defendants that you represent or you're just doing this independently?

MR. TARDIO: No. Howell Allen is a part of the

Tennessee Clinic Defendants.

THE COURT: I see.

MR. TARDIO: So, we represent Howell Allen. These are member physicians of Howell Allen who treated the patients pre- and post-outbreak.

And our position, your Honor, respectfully, is that this information can be established very easily by stipulation or by the medical records or some combination, and we've made an effort to do that, to draft a stipulation and see if it will work.

We did confer on this. This is not -- we didn't simply file this motion reflectively. It was -- we conferred. We drafted a stipulation. The plaintiffs wouldn't agree to it, which is fine. I understand that. But the value of these depositions does not justify the burden and expense on Howell Allen or the individual physicians. The information can be established and presented to the jury just as easily through a stipulation or through the medical records.

THE COURT: All right. Thank you.

MR. TARDIO: Thank you, your Honor.

THE COURT: And I will note that I do think, actually, the parties overall have done a very nice job of conferring. It's not -- we do have that issue in other cases and that doesn't seem to be one. So, I appreciate the effort that goes into it.

MR. TARDIO: Thank you, your Honor.

THE COURT: Yes.

MR. STRANCH: Your Honor, to be very blunt, this is kind of an -- I'm shocked that this motion was filed. It is standard practice that the treating physician be deposed because the treating physician has much more to say than what's limited to the medical records alone.

I can give you a specific example from the Temple deposition yesterday. Temple is one of the Bellwether plaintiffs and his mother died, and one of the things that we learned in the deposition yesterday was that when the doctors came in to tell him, We need to take your mother off of life support, the treating physician was there and participated in that discussion and that was not reflected in his medical records, and that is just one very clear-cut example for why we need to be able to depose these doctors.

And we have searched and I presume the defendants have searched. There is not a single case that we've been able to find in federal or state courts anywhere in the nation that says you can't depose the treating physicians in a personal injury case.

We think that this was brought for delay tactics. You can see that from the email that was sent shortly before they filed the motion for a protective order in which they stated if it's denied, then it's going to take a long time to

schedule these doctors' depositions. This is a further act to try to slow down and stop the plaintiffs from getting to trial, and we believe it is completely without merit and we think the Court should deny it and should order that they be set before January 12th so that we can take these doctors' depositions, and if the case-specific experts need any of that information to include in their individual expert reports, that would give them ten days to incorporate that evidence. We think that's fair. We think that's doable.

I have offered to work with the defendants to try to limit the amount of deposition testimony by stipulating to what we can from the medical records, but we cannot and will not waive our right to take those depositions so that we can get information beyond what is just in the medical records, of which there is much that we would need.

Many of these doctors reached out to the people individually and spoke with them over the phone. What was said in those phone calls could also be relevant. It's also clearly discoverable and is not reflected in medical records.

Frankly, your Honor -- I mean, I'm kind of at a loss for words, to be honest with you, because this is such an obvious example of where a deposition should go forward and it's appropriate.

THE COURT: Thank you. I'll take it under advisement.

So, the next motion is the deposition by written questions; is that correct?

MS. JOHNSON: That's correct, your Honor, and there are two different motions, one pertaining to Box Hill and one pertaining to Premier, but they involve almost identical issues, and Ms. Meeder will be addressing that for the PSC.

MS. MEEDER: Thank you, your Honor.

I presume it's acceptable for me to discuss both the motions --

THE COURT: Yes, please.

MS. MEEDER: -- at one time.

Briefly, the defendants -- specifically, two groups of defendants have noted what amounts to 20 different Rule 31 depositions by written question. Each of those depositions has a list of 21 questions, although many of those questions also involve subparts, and the questions are identical of cross deponents. The clinics involved, the PSC is uncertain as to how those were chosen, but there are 20 separate clinics in Maryland, New Jersey, and I believe also in Tennessee.

The reason -- the PSC's specific request is that these depos are to go forward, that they go forward orally under Rule 30 and not under Rule 31, and the primary reason for this is because Rule 31 is actually a rule that has very limited applicability and it is wholly unsuited to complex matters, such as this case, and, specifically, such as the

issues that are addressed by the questions asked by the defendants.

Really -- you know, Rule 31, if you look back at the caselaw, is something that's been around forever and is very infrequently used at this point. I think maybe we could count on one hand how many attorneys in this room have actually seen these types of notices, but, regardless, the primary concern the PSC has is its inability to adequately follow up and cross question the witnesses without actually being there to hear the responses to their questions and --

THE COURT: Well, you will be there to hear the responses. They give oral responses.

MS. MEEDER: Correct. My understanding, your Honor, is that in advance the PSC is required to submit --

THE COURT: I see.

MS. MEEDER: -- their cross questions and, yes, the deponent is there in person, but counsel is not.

So, essentially, that also prohibits any of the PSC counsel from actually clarifying questions that require clarification and conducting the type of meaningful follow-up that's required and, as we submitted with our briefing --

THE COURT: But I don't think the rule says that counsel can't be present.

MS. MEEDER: You know, your Honor, that may be true, but my understanding is that even were counsel present, they

aren't authorized to ask questions at that time, and that's essentially the type of dialogue that we feel is important for these cases.

And I think, secondarily, that what these depositions really are about are defendant clinics trying to amass a number of other clinics throughout the country, use their procedures or what they did or didn't do to investigate NECC and claim that that somehow creates the standard of care.

The reality is that this deposition -- or these depositions are about the standard of care, and while the defendant clinics will claim that the questions they ask are very specific and are factual in nature, the scope of them is severely limited and doesn't actually allow the PSC to follow up or to further probe what exactly the due diligence was that was or was not conducted and what that standard of care is.

You know, we submitted the depositions that were taken with Brigham & Women's -- I think it's a hospital -- as an example of the type of thorough follow-up that is required in certain instances. The defendants have pointed out that in that instance, Brigham & Women's was known by the PSC in advance to likely have had an in-person investigation take place.

But our point is that regardless of whether these deponent clinics have actually had an in-person investigation of NECC, there continue to be numerous follow-up questions and

cross questions that have to be asked to further draw out what type of diligence was or wasn't conducted and, thus, regardless of whether that inspection took place, the depositions are still not well suited for written question.

THE COURT: Thank you.

MR. WOLK: Your Honor, I'll be addressing that issue, first. Christopher Wolk for the Premier defendants.

THE COURT: I think you need to bring the microphone a little bit closer.

MR. WOLK: I'm sorry. Is it on? How is that? Is that better?

THE COURT: Yes.

MR. WOLK: There we go. Okay. I'm here.

There are 20 questions, and as far as the subparts are concerned -- I'm sure your Honor has looked at the questions and see that the subparts -- the way that the questions are designed is to find out if anything was done at the first step. Was any investigation taken?

Now, if the answer to that question is no, no investigation was taken, then the PSC's argument that it's necessary for thorough and in-depth follow-up fails because if there was no investigation taken, then that's the answer to the question. That clinic did not pursue any investigation of NECC.

What the questions are designed to do is establish at

least one -- not the entire standard of care. Of course, we have experts that can do that, but if we've chosen to take this tactic to discover what other clinics who purchased from NECC did, we can take one portion of that element of the standard of care, which is, did you inspect? And did you do any research? So, to suggest that this --

THE COURT: I'm sorry. Are you suggesting that -- you're using the Rule 31 tool as a way in some ways to screen out clinics that may not have done an investigation and that ones that did do investigation, you will get information pursuant to Rule 31 and then a follow-up deposition?

MR. WOLK: Well, your Honor, I don't know if a follow-up deposition would be requested by the PSC. If after they've got the answers, they see that there was, in fact, an investigation and there were findings, surely, that they are entitled to request from the Court a follow-up deposition for those clinics that have provided those answers.

THE COURT: But doesn't that in some ways then become somewhat inefficient? We're moving quite quickly, I think more quickly than some of the parties would like to, and the thought of having two depositions seems somewhat inefficient, particularly for the clinics that did do a follow-up investigation.

MR. WOLK: In fact, your Honor, the reason we chose Rule 31 was to be efficient in this matter and to narrowly

tailor the questions. They're not so highly technically that I think a follow-up deposition would be necessary. We're simply asking, Did you do an investigation? The answer, no or yes. Did you do research? No or yes. These questions are very narrow so that -- to avoid a follow-up deposition for these questions when they are answered.

THE COURT: I just want to be sure because some of the pleadings suggested a misunderstanding of Rule 31. So, for example, one of the Premier defendants' briefs, the one at Docket No. 2385, says, "Such cooperation will likely vanish if the requests made of these entities become more onerous as by requiring oral deposition rather than allowing written responses."

So, it suggests that whoever drafted that thought that Rule 31 asks for written responses.

MR. WOLK: I think that we clarify that today, that it's the -- Rule 31 is going to be the written questions answered orally, taken down by a court reporter. That will be the process.

THE COURT: Yes.

MR. WOLK: And I thank you for pointing that out. We'll clarify that.

THE COURT: And that's still how you -- knowing that, you still wish to pursue the Rule 31?

MR. WOLK: Yes, your Honor, yes.

THE COURT: All right.

MR. WOLK: So, to just address and be thorough, we don't think that these issues are very complex for a deposition by written question. We think, in fact, that they're very narrowly tailored so that we can efficiently ask -- and at this point eight in my case, because two of the clinics -- one doesn't exist, another one refused service. So, we've withdrawn that subpoena, but that eight clinics who are similarly situated to Premier will be asked questions about whether or not they inspected NECC or did research into NECC, that that narrowly-tailored issue can be answered by multiple non-parties.

And to point out the discussion from the PSC about Rule 31 having a very narrow applicability and only applicable in certain circumstances, the caselaw cited by them really discusses when a party to a case is avoiding a deposition or oral deposition and suggests that a deposition by written question be given instead. That's not the case here. I think the caselaw that is suggested by the PSC is distinguishable in this particular case.

So, with that, we would ask that the motion for protective order be denied.

THE COURT: All right. So, from the PSC's perspective, I understand there may be an efficiency argument, but why aren't you protected if you can have a follow-up oral

deposition?

MS. MEEDER: Well, I think there are two issues with that. One is, as your Honor already noted, the inconvenience and burden to the actual clinic that now has to present for two separate oral depositions, and the scheduling, frankly, involved in that. We're talking about at least a month if we follow the timing and the rule itself before a deposition under Rule 31 is taken, and then we have to get the transcript and potentially documents, and then we have to review whether we believe there should be a written depo -- or I'm sorry -- an oral depo. Then we have to note it. Then we have to schedule it, and we're talking about discovery deadlines that are in March, if not earlier, that we have recently just extended.

So, I think that that's inefficient for a variety of reasons, but what I realize I didn't clarify at the beginning, your Honor, is that there seemed to be also a misunderstanding about what it is the PSC has to demonstrate in order for the Court to be able to require oral as opposed to written depositions.

The defendants' briefing indicated that we were required to show a particular harm, and I don't think that's borne out either in the rules or in the caselaw. Specifically, Rule 26(b)(2)(C)(i), little one, allows the Court to make orders that would change the frequency, extent

or type of discovery, depending on what is least burdensome, most convenient. There actually was formally a provision in Rule 31(d) that permitted specifically the Court to change a written depo to an oral depo. Later amendments took that out because it decided that that was a superfluous statement given Rule 26. So, I just wanted to clarify, too, that there is no need for us to make that showing.

I think also one of the other options the defendant suggested was requiring the clinic to answer direct questions prior to us providing our cross questions, and I think that brings up the same problems that I was just discussing with delay, timing and burden.

Ultimately the least burdensome thing here is for us to simply do an oral deposition. It could be a video deposition. It could be a telephone deposition. People can attend in person or not. And if it's true what defendants are claiming, that these clinics don't have much information in response to the questions, then it will be nice to have a nice short deposition.

But at this point we're -- the clinics that are noticed aren't even necessarily clinics that purchased contaminated MPA. There are actually only two clinics that purchased preservative-free MPA from these lots. There are three that purchased preserved MPA, and the reminder of them, we have no idea what they purchased.

So, the questioning that might be necessary if they purchased, for example, a topical cream as opposed to what we're discussing here, which is a preservative-free steroid injected into the spine, is going to be a very different line of questioning. And the argument in a lot of plaintiffs' briefings has been, in part, that the type of compound that's ordered has an effect on what type of diligence or standard of care is required. So, I think that's an added complexity to what the defendants are asking. So, it's somewhat facetious to claim that these are similarly-situated clinics when, in fact, the majority of them are not.

I just want to make sure I didn't forget anything else, your Honor.

(Pause.)

MS. MEEDER: I just wanted to reiterate what I said earlier, which was that while the defendants believe these are very fact-specific questions, there are a lot of aspects they haven't asked. If they were truly interested in learning what the clinic defendants knew or didn't know at the time that they chose to purchase from NECC, they would have asked them that, but they didn't. They didn't ask them who made the decision. They didn't ask them what the clinic structure is, what the authority is, if they have a general policies and procedures. This type of information is something that's extremely important for us to uncover and it's just not going

to be addressed in what they're describing.

THE COURT: Thank you.

MR. KIRBY: Your Honor, can I just add briefly?

THE COURT: Yes.

MR. KIRBY: To respond to a couple of those statements --

THE COURT: Just for the court reporter --

MR. KIRBY: I'm sorry. This is Greg Kirby on behalf of the Box Hill defendants, and I think Mr. Wolk has something right after this.

But plaintiffs suggest that depositions with written questions is not -- you know, is not the right method to use at this point. I think we can use whatever discovery method we want, and these are not complex matters. You know, what we're trying to ask are questions, you know: Did you travel to NECC to inspect? Did you submit a FOIA request? We're not trying to find out what their -- you know, what every policy and procedure is. They're not parties. They're non-parties. If the Plaintiffs' Steering Committee wanted to do full-blown depositions before, they could have done it and they haven't.

This is information that we can use to bolster our defenses in this case and that's the same argument that the PSC used back in 2013 when they sent about 90 subpoenas to non-parties seeking a whole host of information, and there were many objections, as I'm sure you're aware from two years

ago, and one of the things they explain was that they narrowly tailored their request to make it the least burdensome and expensive on the non-parties, which is what, you know, we're trying to do -- what we're trying to do now.

You know, from a *Daubert* motion's perspective -- there are likely to be *Daubert* motions later -- this is information that would help us. We're not seeking to find out -- you know, to prove the standard of care, you know, but if they're going to have an expert to come in and say that the standard of care is -- the standard of due diligence required X, and then we have evidence that shows that, you know, everyone -- or the large majority, you know, didn't do X, then that -- you know, that supports that kind of an argument.

They mention the Brigham & Women's deposition, which was a long and detailed deposition, but Brigham & Women's did an inspection. We anticipate that all or most of these entities didn't do inspections. And so, it will be a simple, no, I didn't do an inspection, and we move on to the next question. It doesn't require a lot of follow-up about what -- you know, what you found when you did the inspection, which is what they would like to get at. Thank you.

MR. WOLK: I'll be very briefly, your Honor, just to address two points.

The PSC is making the argument that why don't we just go ahead and take all these depositions and have an oral

deposition.

And just to the efficiency argument, I'm not trying to set these depositions by written questions so that we have follow-up depositions. And you're right, that's two steps in the process we don't have to take, but if there happens to be follow-up depositions, there will likely be less -- more likely than not, be less than eight depositions in follow-up. So, the actual work that will have to be done to get the oral depositions will be less than if we at the outset just took eight depositions from the beginning and then ten from Box Hill. That's 18 depositions.

The PSC mentioned questions about who ordered the medications? What was the process? What policies and procedures were in place? They have an opportunity under this rule to submit cross-examination questions and they sound like good cross-examination questions to me that they could submit and have answered.

THE COURT: All right. Thank you. I will take it under advisement. So -- yes. Someone else? No. Okay.

The next one, Ms. Johnson.

MS. JOHNSON: Thank you, your Honor.

The next two motions are actually similarly related. They both involve efforts to compel compliance with the subpoena issued to Dr. O'Neal, and Mr. Stranch will be addressing that for the Plaintiffs' Steering Committee.

THE COURT: And just for purposes of the record, I believe we have someone on the phone who is going to argue this. Could you identify yourself for the record at this time?

MR. ELLIOT: Yes. Good morning. Steve Elliot on behalf of Mr. O'Neal.

THE COURT: All right. Thank you.

MR. STRANCH: Good morning again, your Honor.

Dr. O'Neal is a pharmacist who works at Vanderbilt and is the pharmacy consultant to STOPNC, and we sent the subpoena to Dr. O'Neal, and we think once you get through all the briefing, the issue is basically resolved, because Dr. O'Neal has agreed to sit for a deposition and to produce documents. He's agreed to answer questions without asserting the privilege as to the 2007 O'Neal contract and the second O'Neal contract. These are the two contracts that were entered into that define his relationship with STOPNC.

The questions are important because one of the issues is, when does the second contract go into effect? It's dated by one of the parties September 2012, but it was not signed by Dr. O'Neal until April of 2013, which also happens to be the same time that some of these issues were being litigated in state court. It also happens to be the same time that the document formulary at Specialty Surgery, which is another defendant in this case, represented by the same counsel as the

clinic defendants, was being modified without the plaintiffs being told. A lot of activities happening in April of 2013 and we should be able to question about that in this contract.

The questions about when they became effective and everything around them, he's agreed to testify on that. Questions about alleged inconsistencies between the testimony of any of the witnesses and the contracts because that already exists, as we've put into the record to the Court, and then questions about any recommendations made by Dr. O'Neal prior to STOPNC's purchase of any particular medication, and we believe those are appropriate topics and that basically resolves the motions, and we're ready to set his deposition for hearing and go forward on it.

If the Court has specific questions, I'm happy to delve into each one of the reasons as to why we should go forward, but between Dr. O'Neal and the plaintiffs, we've resolved this.

THE COURT: So, I know both parties have assumed that Tennessee law applies and, obviously, there's pending briefing before Judge Zobel, and I have no inside intelligence as to when she may decide that issue. So, does it make a difference to you if she decides that Massachusetts law applies to these cases with respect to this motion?

MR. STRANCH: Yes. From my perspective, your Honor, the Massachusetts law is not -- it's not going to affect it.

If anything, it's going to make this a simpler call, but the reality is with the agreement that we've reached with Dr. O'Neal and what he will testify to, we can go forward whether it's under Massachusetts or Tennessee law and the plaintiffs are happy to take those topics.

THE COURT: And I may have missed this, but -- so, there are various time periods, right? There's the time period before and after the enactment of the -- I'll call it the second privilege log. There's the two contracts and then there's the dates within the second contract, right? So, we have lots of different overlapping dates.

MR. STRANCH: Correct.

THE COURT: I wasn't sure if I heard you to say at this point are you not asking -- you are not going to ask Mr. O'Neal about activities that are potentially covered by the second privilege log?

MR. STRANCH: So --

THE COURT: Because that didn't seem to be resolved by the -- between the PSC and Mr. O'Neal.

MR. STRANCH: Well, what we've agreed to is we're going to get the answers to the questions about when certain contractual obligations went into effect, because one of the things you have to do is, you know, for a certain period of time you have to have been reporting to a specific committee and hired to work for that committee, and the contract doesn't

say that he was hired to do that. The second contract does, but it went into effect long after everything else. And, in fact, our questions -- the most important ones to us all predate that September 12th date when the second contract went into effect.

Now, the new privilege log did go into effect in 2011, but in our back-and-forth with Dr. O'Neal, what we've agreed to is we would limit our questions to recommendations that Dr. O'Neal made prior to Saint Thomas Neurosurgical's purchase of a particular medicine. And so, by doing that, it falls outside of any potential privilege issue, and Dr. O'Neal is happy to testify on that. In fact, Dr. O'Neal has stated that he looks forward to clearing his name, as I understand it.

THE COURT: And, again, this may be a moot question if you have actually resolved all the issues, but, in your view, whose privilege is it to invoke?

MR. STRANCH: I believe the privilege belongs to the individual being deposed here, which is Dr. O'Neal. The clinic is, obviously, trying to assert the privilege themselves and say that, but when you read through it, it says there's a healthcare organization and all that and -- but it's really kind of immaterial, your Honor, because we don't believe our questioning falls within the privilege, anyway, nor does Dr. O'Neal.

THE COURT: The second --

MR. STRANCH: That's correct.

THE COURT: Or either privilege.

MR. STRANCH: And so, we believe that with this agreement, you know, there's no worry about it crossing into the privilege because we're asking him questions about when he entered into contracts, which is clearly not going to be covered by the quality improvement process, and they're required to have a pharmacist on staff.

And so, we can ask him, you know, Did you do this? And if Dr. O'Neal's response is going to be, your Honor, as we suspect, No, they didn't consult me and so, I didn't render any advice on that, that's not protected by the quality improvement process because it's not nothing that he gave to them. So, it would fall outside the privilege regardless.

THE COURT: All right. Mr. O'Neal's lawyer, are you in agreement with what the PSC said as to the agreements with respect to the deposition?

MR. ELLIOT: Yes, your Honor. This is Mr. Elliot for Dr. O'Neal.

We filed a response where we outline the areas in which we will not invoke the privilege as well as the contentions that we're not making, and I haven't heard any argument about retroactivity. We have not taken a position one way or the other about whether or not the -- what I'll call the newer peer review statute applies retroactively, and

I'm going to leave that to the STOPNC defendants to make that argument. We just don't take a position either way. So, I quibble a little bit when the plaintiffs commented in a pleading where they have said that we have agreed on that issue. We have not.

So, I think, in large part, we have agreed on the issues. We'll produce a privilege log. I think that the privilege applies both ways. Mr. O'Neal is a quality improvement committee. The statute says an individual -- one or more individuals can be one, and he is, and he's working at the behest of STOPNC. So, I think both STOPNC and Mr. O'Neal can invoke the privilege to the extent they feel it necessary.

THE COURT: And my same question to you. If Judge Zobel should rule that Massachusetts law applies, does this issue go away?

MR. ELLIOT: Your Honor, I've not seen that, and you may have seen from our briefing that we anticipated, perhaps, an argument from the Plaintiffs' Steering Committee that federal law in some regards should apply, and I think you have agreement from both sides that Tennessee law should apply here. This was a Tennessee pharmacist providing consulting services to a Tennessee clinic and to apply Massachusetts law, we would respectfully submit, is not the right way to go.

THE COURT: All right. So, for the Tennessee folks -- it sounds like everyone else is in agreement, but you

don't want the deposition to go forward?

MR. TARDIO: Well, I don't disagree that Mr. O'Neal can testify as to when the contract was put in place, why he signed it in April versus September. Generally discussions about what his relationship was, were you the pharmacy consultant from X date to Y date? Why did you change the contract in 2012? Things of that nature. So, that's, I think, as I understand it, the first category of agreement.

The second category being alleged inconsistencies between the two contracts. I think that's a fair area of inquiry.

The third area of inquiry, any recommendations made by Dr. O'Neal -- or Mr. O'Neal before buying the medication. Any substantive recommendations he made as part of his pharmacy consulting role are plainly covered by the privilege. They are. He's --

THE COURT: Both privileges?

MR. TARDIO: They're certainly covered by the second privilege. I think they're covered by the first privilege, too, and I would respectfully submit that the second privilege applies retroactively under the law of Tennessee. The law of Tennessee says remedial and procedural statutes apply retroactively. This is a procedural statute. It deals with what evidence is admissible at trial and what is discoverable, and Tennessee has defined procedural to include statutes about

evidence.

So, I believe that certainly under the second iteration of the statute, any substantive recommendations made by Mr. O'Neal before buying medications would be covered, and I don't know that that's what -- I don't want to speak for Mr. O'Neal's lawyers, but if the answer to that question is, no, I didn't do it, then I think that's fair. It's a negative. There's no substance there. There's no information to protect by privilege, but if there were recommendations made, those are covered by the privilege.

THE COURT: I had understood your argument to depend on a characterization of the second privilege statute as remedial.

MR. TARDIO: Or procedural.

THE COURT: And are you still arguing remedial as well?

MR. TARDIO: Yes. In Tennessee law, it's clear that remedial or procedural in some cases --

THE COURT: No. No. I just thought all you had argued was procedural, because in support of the remedial argument, you had only cited as authority a law firm Internet article.

MR. TARDIO: Well, that's not true. I think that -- I didn't anticipate any pushback on the fact that this law was passed in response to the *Lee vs.* -- *Lee Medical vs. Beecher*

case. I thought that was accepted. If that is not accepted by everybody in this room, then I'm happy to try to dig up the legislative history.

THE COURT: That's my next question. Do you know if there's anything in the legislative history?

MR. TARDIO: I don't know. Probably, because it was pretty plainly in response to the Supreme Court decision, but I'm happy -- if that's something that the Court is curious as to, I'm happy to dig it up because I believe it's probably there, but I can't say for certain.

But Tennessee law uses remedial and procedural interchangeably when they're talking about retroactivity, and I think it's both remedial and procedural.

THE COURT: Are you still arguing that the Tennessee state court judge's decision operates essentially as collateral estoppel?

MR. TARDIO: Yes, your Honor. It operates to preclude re-litigation of this issue, which is basically what collateral estoppel or issue preclusion is. We feel strongly that all of the elements under Tennessee law are met and that the Tennessee state court decision on this exact issue should be given preclusive effect.

THE COURT: But isn't one of the elements that the decision is final and in many jurisdictions, a voluntary dismissal renders a preliminary decision not final for

purposes of collateral estoppel?

MR. TARDIO: I think that is the general rule when you talk about claim preclusion. If we had a judgment, a dismissal of the entire case on the merits or a decision by the jury and we were arguing that this entire second claim should be barred, I do think that a voluntary dismissal is not a final decision. When we talk about issue preclusion, as I read the caselaw, the caselaw we cited, the operative inquiry for the Court is whether the issue was finally decided, and we believe the issue -- the issue was finally decided even if the claim was not.

THE COURT: And I think I can guess what your position is, but who do you think can invoke the privilege here?

MR. TARDIO: I think it's our privilege. I don't know of any caselaw under the new statute as to who owns the privilege, but I'm comfortable that we in receiving -- in engaging Dr. O'Neal, Mr. O'Neal, and receiving substantive quality improvement consulting, that it's our privilege to invoke.

THE COURT: And is there any caselaw under the old statute?

MR. TARDIO: I think so. I don't --

MR. GIDEON: There's a specific case under the old statute and the title of the case is *Powell vs. Community*

Health Systems, a decision by the Tennessee Supreme Court on the same day as the *Lee Medical* case, and one of the five holdings in that case is that an individual cannot waive the peer review statute that existed at the time.

THE COURT: Thank you.

MR. GIDEON: Yes.

THE COURT: I did have a question for the PSC about the document request associated with the deposition notice. So, it seeks documents from January 1, 2000, but my understanding is Mr. O'Neal didn't start work in this capacity until 2007.

MR. STRANCH: We're happy to limit it to 2007. When we sent it, we didn't know the date which he actually began working with the clinic.

THE COURT: And then it asks for all documents related to NECC and then all documents related to various drugs. That seems rather broad. What specifically are you looking for there?

MR. STRANCH: Specifically, what we really want to get to with Dr. O'Neal is the MPA and whether he evaluated NECC and if he did, whether he also evaluated before the purchase of the preservative-free MPA from NECC.

THE COURT: All right. Thank you. All right. I will take that under advisement.

And what's next, Ms. Johnson?

MS. JOHNSON: That's all, your Honor, unless you separately wanted to hear the O'Neal motion for protective order, but I think we've covered that in the last --

THE COURT: I think we have.

From Mr. Elliot, anything further on this issue?

MR. ELLIOT: No, your Honor. I think we covered that well enough.

THE COURT: All right. And, Mr. Tardio, I feel we've gone over the appropriate ground, but I'm happy to hear you on anything else on this.

MR. TARDIO: The only thing I would add, your Honor, I don't think we addressed, from our perspective, whether Massachusetts law applied --

THE COURT: I didn't ask you that, you're right. I'll give you a fair opportunity.

MR. TARDIO: It's the same position, I believe, as the other two parties' argument on this -- or the nonparty arguing on this point. I think that Judge Zobel considered whether Massachusetts law applies to the comparative fault claims against the NECC folks. So, I don't think it has any impact on this motion.

THE COURT: All right. Thank you.

I had a couple of questions based on other filings. There are a lot of motions for access to the Rust and Omni depositories, and I saw in the schedule that the PSC

anticipated filing an omnibus response.

So, I understand that it's not fully briefed and that the PSC wanted to weigh in in writing, but is it a question of whether they should have access at all or is it a question of the proper form for them to have -- or procedures?

MS. JOHNSON: It's a couple of things, your Honor. We do not substantively oppose access. There are certain parameters that we think are required be put on certain parties' access to particular documents.

One issue is that there are some documents in that repository that were produced pursuant to an order of the bankruptcy court that required clinics to produce lists of patient names for purposes of issuing notice of the bar date way back when, and the bankruptcy court order limits access to those documents to -- I think it's the trustee, the now disbanded creditor's committee and plaintiffs' lead counsel. So, that's one of the issues, but substantively there is no broad opposition to access. It's just a question of crafting it correctly.

And to be very blunt about it, your Honor, the reason we've not yet filed that is I wanted to make sure that my firm as lead counsel has access to the Rust repository in its entirety. I wanted to make sure that we took a look at what was there and were educated ourselves enough about it and how the repository worked so that we could include that

information in our response.

THE COURT: So, I'm just wondering in terms of efficiency. It doesn't sound like I will -- is it the Box Hill folks that are seeking it and lots of other counsel or --

MR. STRANCH: Just Premier.

THE COURT: Premier?

MR. WOLK: We will join -- I join --

THE COURT: Everyone?

MS. JOHNSON: Everybody.

THE COURT: Would it be most efficient to go forward by -- assuming that you're not opposing access, to drafting an order for my signature, hopefully, getting everyone's consent and if not getting everyone's consent, presenting me with the competing orders?

MS. JOHNSON: I think that would be perfect, your Honor, in terms of a procedure forward.

THE COURT: At least from the folks that are here, does that work for you? It just seemed to me I shouldn't wait for oral argument. I should, if we can work it out, sign the orders and get you access where appropriate.

MR. KIRBY: Your Honor, Greg Kirby. Box Hill defendants.

I'm fine with that approach, but I think you said get consent of the parties. So, as long as I can see the proposed order first to make sure that --

THE COURT: That's what I meant. I mean, I don't think everybody needs to see it. I mean, I assume everyone is welcome to see it, but it seems to me that the parties who have moved and the PSC, if you all can come to an agreement, I can sign it and you can be on your way.

MS. JOHNSON: And so, it may be helpful to flag for the Court a couple of the PSC's potential issues so that we don't have to come back here and hear argument, which I hate to do.

One issue is that whether it is appropriate for one clinic or counsel for -- involved in a particular set of cases to have access to documents produced by other clinics that would otherwise -- you know, may be unrelated -- not just unrelated, but irrelevant, and because this is HIPAA-protected information, it's something that the PSC has thought a lot of about in light of all the previous caselaw here and the order as originally crafted. So, that's one issue to be resolved.

Another, as I said, is that there's this order in the bankruptcy court that applies to a small section of documents that are in the repository.

A third has to do with the structure of the repository. This is not -- so, to contrast it, we have two repositories in this case: One is hosted by U.S. Legal, the other is hosted by Rust. The U.S. Legal repository is -- at least from the PSC's perspective -- defendants may disagree --

a fairly sophisticated, searchable, easily navigable platform that we set up, knowing lots of people would want access to it and to use that platform itself. The Rust repository, my understanding, is it's not. It's not as sophisticated. These documents are not all searchable. I think they're all produced in native format. We will confirm that.

So, because of some of those limitations, there's a question about how you might properly craft access to some documents versus others, because I don't believe that it's possible, for example, to run a patient's name through that repository and get hits that we could then produce to lawyers involved in those cases.

So, again -- so, just to flag for the Court, those are some of the issues. I do think we can work through those and I think we can craft a protective order that I think the defendants will agree to as well.

MR. KIRBY: Your Honor, just one brief comment.

I'm not against that at all. She mentioned unrelated information from other clinics, and by principle I don't want information or need information from some other clinic about, you know, HIPAA-sensitive medical records, but at the same time, the devil is in the details as to who is determining what's related and unrelated. Just a preview. We'll play nice with one another.

THE COURT: I appreciate the preview and, hopefully,

you can work it out and if not, I'm confident you will give me separate proposals for me to examine.

MS. JOHNSON: And we will try to do that quickly, your Honor. My paralegal who is most knowledgeable about the repositories has been out this week, but will be back after the holidays. So, we'll get to the defendants shortly after the first of the year and try and work through that.

THE COURT: And my last point or topic -- and I'm happy to hear from you all if you have anything else -- is scheduling. I have -- with respect to the January 14th conference, I did have a trial scheduled that week. That trial is not -- no longer going forward on that week. So, I am available on the 14th. I'm not available that morning, but I could hear folks, if there's anything to be heard, after Judge Zobel concludes her session. I assume that's preferable to folks because it may save on some travel time, but is there any objection, at least from the folks here -- I'll mention it at the next conference as well -- to me moving the January 15th conference to January 14th in the afternoon?

MS. JOHNSON: Preferable for the plaintiffs, your Honor. Thank you.

MR. WOLK: No objection.

THE COURT: All right. And then on February 11th, now, that week I do have a trial scheduled in the morning. So, I would propose doing a similar thing and moving that

conference, if there's anything to be heard, to 4 o'clock or whenever Judge Zobel finishes. Is that -- are there any objections from the folks here to doing that?

MS. JOHNSON: No, your Honor.

MR. WOLK: No objection.

THE COURT: So, I'll raise that again at the conference this afternoon.

Is there anything else from the PSC?

MS. JOHNSON: Just to say, your Honor, I know all of the lawyers in this room and the parties generally are very aware of and appreciative of how much work this Court has done in the last few months turning through these discovery motions and just on behalf of everyone, we very much appreciate it.

THE COURT: Well, it helps when there's good counsel. So, it makes the decisions -- they're not always easy decisions, but at least I have the right tools to reach the decisions. Yes. Anything else?

MR. GIDEON: Yes, your Honor. I would like to just ask a question regarding the Court's order of December 10th, 2015, which addressed the depositions of John Notarianni and Joseph Connolly.

THE COURT: Yes.

MR. GIDEON: You will recall that your Honor, with an electronic entry, overruled the USA's order -- motion to stop those depositions in perpetuity. There was a subsequent

opinion that was released a day or two later that said that the stay continued to be in effect until December 17th.

I spoke with lead USA -- Assistant USA counsel that Friday afternoon. We filed the notice reflecting the depositions would not occur. As of that day she wasn't sure if she was going to file anything.

And my question is, the last line of -- the next-to-the-last line of the order provides that the government has permission to file any such portion of such motion that it deems necessary ex parte and under seal.

In the event that the United States does that, will I be -- will I have access to what has been submitted to you in any format so that I may in any way attempt to convince you to allow me to proceed with those two depositions?

THE COURT: I think that will depend on what is submitted. I would seek the government's counsel on that, whether it could be shared with you versus public dissemination, I think, is the two. So, why don't we reach that issue when we get to it.

MR. GIDEON: We'll wait to see if she files anything by the end of the day today.

THE COURT: Ms. Strackan, do you wish to comment?

MS. STRACKAN: Sure, your Honor.

THE COURT: Maybe you could sit at that table.

MS. STRACKAN: Sure, I'm happy to.

THE COURT: Sorry. I know you're on the fly.

MS. STRACKAN: That's all right.

I'm Amanda Strackan from the U.S. Attorney's Office.

We do plan to file something with your Honor today. To the extent that there is information that can be shared publicly on the public docket, we will do that. I think the plan at this point will be to file a motion -- a motion on the public docket, saying in that what we feel can be part of the public record and then making an ex parte under seal filing for your Honor that contains information that we believe is properly under seal and ex parte. So, I think it will be in two parts and, obviously, the plan will be to only include things in the under seal ex parte filing that deservedly should be there.

THE COURT: All right. And my understanding, for purposes of clarification, is that the government intends at this point what it would file under seal not to be shared with any of the other counsel in this case?

MS. STRACKAN: That's correct, your Honor.

THE COURT: All right.

MR. GIDEON: Can I not ask her to make just one exception for me with respect to the --

THE COURT: I'll let you try -- yes, you're welcome to ask her and you're welcome to have that discussion, but I will be guided by the government's filing, unless I think it's

not appropriate, but -- and in that instance, if I thought it was not appropriate to be under seal, I would either have it returned to the government and say I will not rely on it unless they were willing to file it on the record or I won't.

MR. GIDEON: I understand.

THE COURT: So, those are the options.

MR. GIDEON: Thank you.

THE COURT: All right.

MS. STRACKAN: One last thing, your Honor, I had intended to bring up this afternoon that may be helpful.

There is a stay of discovery in cases against what we call "small clinics," so clinics where there are -- I think it's four or fewer cases in the MDL. That stay expires -- I believe it's December 31st, but, in any event, before the next status conference, and I would anticipate that you will see a filing -- I think we will do it formally -- from the PSC and, hopefully, to be joined by counsel for small clinics, asking the Court to formally extend that deadline, at least so that we don't have a flurry of discovery requests issued on the 1st of January.

THE COURT: All right. So, I will act on that as quickly as I get it.

All right. Thank you. I'll see you all later.

COURTROOM DEPUTY CLERK YORK: All rise. The Court is in recess.

(Adjourned, 12:31 p.m.)

C E R T I F I C A T E

I, Catherine A. Handel, Official Court Reporter of the United States District Court, do hereby certify that the foregoing transcript, from Page 1 to Page 43, constitutes to the best of my skill and ability a true and accurate transcription of my stenotype notes taken in the matter of Multidistrict Litigation No. 13-02419-RWZ, In Re: New England Compounding Pharmacy Cases Litigation.

December 22, 2015 /s/Catherine A. Handel
Date Catherine A. Handel, RPR-CM, CRR